

## REMARKS

The present Office Action addresses and rejects claims 1-22. Reconsideration is respectfully requested in view of the amendments and remarks submitted herein.

### *Amendments to the Claims*

Applicants amend independent claim 1 to clarify that the plurality of secondary catheters are coupled to one another and to include the limitation present in original claim 14, now cancelled, that the fluid entry ports are inwardly facing. Support for this amendment can be found throughout the specification and in the drawings, for example, at page 10, lines 18-20 and in Figure 4A. Independent claim 16 is also amended to clarify that the plurality of branch conduits are coupled to one another, and to further recite that the catheter is configured to removably receive a rigid stylet through the inner lumen of the elongate trunk and between the plurality of branch conduits. Support for this amendment can be found throughout the specification and in the drawings, for example, at page 10, lines 18-20, page 11, line 23 to page 12, line 2, and in Figure 4A. Claim 20 is amended to recite *at least one* connector bracket. No new matter is added.

Applicants also add new claims 23-27, support for which can be found in original claims 1-22 and throughout the specification and in the drawings. No new matter is added.

### *Claim Rejections*

#### (1) *Claims 1-15*

Independent claim 1, as well as dependent claims 3, 6, 8, and 15, are rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,925,452 of Melinyshyn et al. (“Melinnyshyn”). The Examiner also rejects several of the dependent claims pursuant to 35 U.S.C. §103(a) as being obvious over Melinyshyn taken alone, Melinyshyn in view of U.S. Patent No. 4,432,853 of Banks, or Melinyshyn in view of Banks and further in view of U.S. Patent No. 4,406,656 of Hattler et al. (“Hattler”).

Independent claim 1 recites an implantable catheter having a primary catheter and a plurality of secondary catheters coupled to one another and having inwardly facing fluid entry ports formed

therein. None of the cited references teaches or even suggests a plurality of secondary catheters *coupled to one another* and having *inwardly facing fluid entry ports* formed therein.

Melinshyn discloses a drainage device having multiple conduits that are joined to one another by two membranes which extend along the length of the conduits. Each conduit also includes a plurality of drainage holes formed therein. As shown in Figure 2, the drainage holes (22) are formed in outer surfaces of the conduits. This configuration is necessary because the inwardly facing surfaces of the conduits are mated to one another by the two membranes (26, 28) that extend along the length of the catheter. Accordingly, Melinshyn does not teach or even suggest a plurality of secondary catheters coupled to one another and having *inwardly facing fluid entry ports*, as required by independent claim 1 of the present invention. Claim 1, as well as claims 2-13 and 15, are therefore not anticipated by Melinshyn.

Neither Hattler nor Banks remedy the deficiencies of Melinshyn. At the outset, claim 1 is not obvious over Melinshyn in combination with *any* reference because it would not have been obvious to a person having ordinary skill in the art to modify Melinshyn to include inwardly facing fluid entry ports due to the mating configuration of the conduits, i.e., the inwardly facing surfaces are mated to one another. The catheter disclosed by Melinshyn is also specifically configured for use in surgeries, such as abdominal surgery, in which blockage of the ports is not of any particular concern. Regardless, neither Hattler nor Banks teach or even suggest secondary catheters coupled to one another and having inwardly facing ports.

Hattler is directed to a venous catheter having a plurality of collapsible lumens. The catheter does not include any inlet ports formed in the sidewall thereof, much less inwardly facing inlets ports, as required by independent claim 1. Hattler therefore does not remedy the deficiencies of Melinshyn. Applicants also note that Hattler cannot be combined with Melinshyn or Banks because Hattler is directed to a fluid *delivery* catheter. Fluid flow through the catheter is required to inflate the collapsible lumens. No person having ordinary skill in the art would rely on a reference directed to a collapsible fluid *delivery* catheter to modify a fluid *drainage* catheter. The two devices have distinct configurations that are specifically designed to perform distinct functions.

Banks also fails to remedy the deficiencies of Melinshyn. Banks is directed to a catheter

having microtubules with multiple microscopic perforations formed in the sidewall thereof. As shown in Figure 1, the microtubules are not coupled to one another and thus they do not include inwardly facing ports formed thereon, as required by independent claim 1. Applicants further note that it would not have been obvious to modify Banks to couple the microtubules to one another and to include inwardly facing ports. Applicants have discovered that by coupling the secondary catheters to one another and including inwardly facing ports, debris and other matter is prevented from growing into the ports or otherwise blocking fluid flow through the ports. Modifying the Banks catheter to couple the microtubules to one another and to include inwardly facing ports is not necessary because Banks already provides a solution to prevent blockage. In particular, Banks provides a catheter having multiple *microscopic* perforations with diameters ranging from about 14 microns to about 150 microns. The microscopic size of the perforations prevents debris and other matter from entering the perforations and thereby causing blockage of fluid flow through the catheter. Moreover, “[t]he small diameter of the perforations 18 reduces the probability of cerebrospinal fluid flow blockage caused by localized collapse of the ventricle.” (Banks, Col. 4, lines 43-45.) Accordingly, because Banks provides a catheter that overcomes problems resulting from blockage of the ports, it would not have been obvious to a person having ordinary skill in the art to modify the Banks catheter to couple the microtubules to one another and to include inwardly facing inlet ports to prevent blockage of the ports, as required by independent claim 1 of the present invention.

Independent claim 1 therefore distinguishes over Melinyshyn, Hattler, and Banks, taken alone or combined, and represents allowable subject matter. Claims 2-13 and 15 are allowable at least because they depend from an allowable base claim.

(2) *Claims 16-22*

Independent claim 16, as well as dependent claims 17 and 20-22, are rejected pursuant to 35 U.S.C. §102(b) as being anticipated by Melinyshyn. The Examiner also rejects several of the dependent claims pursuant to 35 U.S.C. §103(a) as being obvious over Melinyshyn in view of Banks, or Melinyshyn in view of Banks and further in view of Hattler. Applicants submit that none of the cited references teaches or even suggests the claimed invention.

Independent claim 16 recites an implantable catheter having a trunk conduit and a plurality of branch conduits that are coupled to one another and that extend from the trunk conduit. Claim 16 further requires that the catheter be configured to removably receive a rigid stylet through the inner lumen of the elongate trunk and between the plurality of branch conduits. None of the cited references teaches or even suggests such a feature.

Melinshyn does not teach or even suggest a catheter that is adapted to receive a stylet, and the use of such a stylet would not have been obvious to a person having ordinary skill in the art. In particular, the Melinshyn device is intended for use in surgeries such as stomach surgery. As a result, the catheter can merely be positioned at the desired implant site prior to suturing the wound. Accordingly, a rigid stylet would not be necessary to facilitate insertion of the device into an implant site. Melinshyn therefore cannot be modified for use with a rigid stylet, as required by independent claim 16, and therefore claim 16 distinguishes over Melinshyn, taken alone or combined with any other reference.

Hattler likewise fails to teach or even suggest the use of a removable rigid stylet, and thus Hattler does not remedy the deficiencies of Melinshyn. The Examiner refers to the guide 800 shown in Figure 8 of Hattler as being a rigid stylet, however the guide 800 is fixedly attached to the collapsible lumens and it is an integral part of the device. The guide provides support to the collapsible lumens, allowing the lumens to collapse there around during insertion of the device. As stated in the detailed description of Hattler, “[w]ithout the provision of the central lumens or a guide 800, the collapsible lumens of the present invention would run the risk of being kinked or bent at one or more locations and thereby prevent the proper flow of fluids either into or out from the vein 30.” (Col. 6, lines 45-50.) Hattler further states that “[w]ithout this, structural support, the collapsible lumens would be difficult to handle.” (Col. 6, lines 57-58.) Accordingly, the guide is necessary and it cannot be removable, as required by independent claim 16 of the present invention. It further would not have been obvious to a person having ordinary skill in the art to modify the catheter of Hattler to include a removable stylet because Hattler already provides a rigid support for insertion of the device, and because removing the guide would render the device inoperative, as suggested in the specification of Hattler.

Applicants also note that, for the same reasons discussed above with respect to claim 1,

Hattler cannot be combined with Melinyshyn or Banks because Hattler is directed to a fluid *delivery* catheter and no person having ordinary skill in the art would rely on a reference directed to a collapsible fluid *delivery* catheter to modify a fluid *drainage* catheter.

Banks also fails to teach or even suggest an implantable catheter having a removable stylet that extends through the central lumen of the trunk conduit and between a plurality of branch conduits. Moreover, as previously discussed above with respect to claim 1, Banks fails to teach or even suggest secondary catheters coupled to one another, as required by claim 16. Banks therefore does not remedy the deficiencies of Melinyshyn.

Accordingly, independent claim 16 distinguishes over Melinyshyn, Hattler, and Banks, taken alone or combined, and represents allowable subject matter. Claims 17-22 are allowable at least because they depend from an allowable base claim.

### ***Conclusion***

In view of the amendments and remarks above, Applicant submits that the pending claims are in condition for allowance, and allowance thereof is respectfully requested. Applicant encourages the Examiner to telephone the undersigned in the event that such communication might expedite prosecution of this matter.

Respectfully submitted,

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